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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,376	08/29/2003	Carl E. Fabian	0018-13	7325

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EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b> 10/650,376	<b>Applicant(s)</b> FABIAN, CARL E.	
	<b>Examiner</b> Michael G. Bogart	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

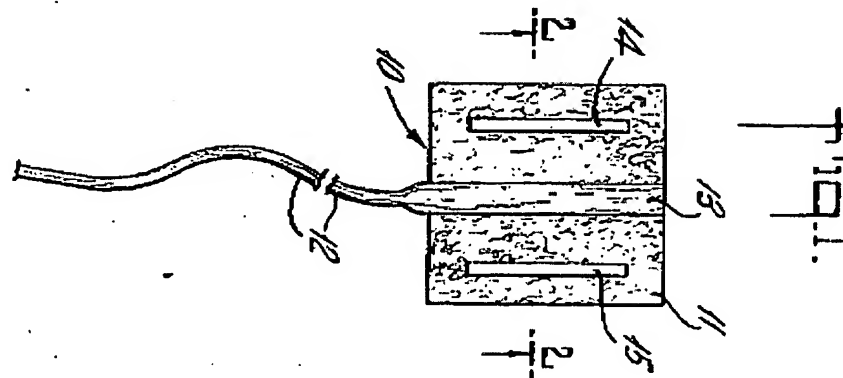
### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 15 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reimels (US 3,736,935).

Regarding claims 1-6, Reimels teaches a surgical sponge (10) comprising a plurality of radiopaque markers (14, 15), including barium sulfate, the markers disposed in a substantially fixed relationship (col. 2, lines 48-59)(see fig. 1, below).



Ballard is silent as to the specific density or size of the markers.

Mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. *In re Rose* , 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims

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directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In the instant case, it is well known in the art that increased density and size of a barium marker increase its ability to be detected by an X-ray. (*see, e.g.*, Dyer, US Pat. No. 4,639,253, col. 3, lines 4-12).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to maximize the size and/or density of a barium sulfate marker in a surgical sponge in order make it more readily detectable by an X-ray.

Regarding claims 7 and 9, Reimels teaches a marker (14, 15) having distinctive linear shapes, which are detectable by an X-ray.

Regarding claims 8, 10 and 15, mere changes in shape are not sufficient to patentably distinguish an invention over the prior art. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). See Ballard (US 6,777,623 B2) which teaches a substantially spherical marker (401).

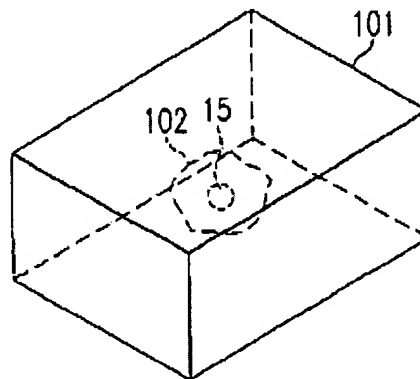
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Regarding claim 16, Reimels teaches that more than two markers may be employed (col. 2, lines 48-59).

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Reimels as applied to claims 1-10, 13 and 14 above, and further in view of Ishikawa *et al.* (US 6,366,206 B1).

Reimels does not teach an electronic tag.

Ishikawa *et al.* teach a surgical sponge (101) with an electric transponder (15)(see fig. 7, below).



**FIG. 7**

At the time of the invention, it would have been obvious to add the electronic transponder of Ishikawa *et al.* to the surgical sponge of Reimels in order to provide a remote means of tracking the sponge (abstract; col. 8, lines 42-51).

Claims 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reimels as applied to claims 1-10, 15 and 16 above, and further in view of *Uncommon Peril of Forgotten Surgical Tools*, Davis Grady, The New York Times, Jan. 21, 2003 (hereinafter “Uncommon Peril”).

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Reimels does not disclose expressly the steps of x-raying a patient and removing a surgical sponge thereafter.

*Uncommon Peril* teaches that a patient suspected of having a surgical sponge or other implement having a marker inside them can be x-rayed and if the implement is found to be there, it can be removed.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-11 and 13-16 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
9 February 2006

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

